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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,165	11/19/2001	Michael Zeppezauer	44011.010700	8263

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/988,165	ZEPPEZAUER ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005 and 22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1 and 2, filed 10/11/05, and the peptide species: $1_{(4)}$, SEQ ID NO:6, filed 8/22/06, is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 3-14 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.

Claims 1 and 2 are being acted upon.

3. The specification is objected to for the introduction of new matter into the specification. In the instant amendment at pages 12 and 13 Applicant has added pharmaceutical compositions comprising numerous peptide species that do not appear in the specification as filed.

4. A substitute specification excluding the claims was previously required. A substitute specification was filed on 10/11/05. Said substitute specification, however, includes numerous spelling errors, e.g., "autoimmun" (page 1 and elsewhere), "abject" (page 2), "histon" (page 4 and elsewhere), etc., such that an additional substitute specification is required.

Applicant is further advised that the priority data at the first line of the specification requires updating.

5. The declaration is objected to because numerous uninitialed changes have been made. A new declaration is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) In Claim 1, numerous non-elected inventions are recited.

B) In Claim 1, the phrase, "hormonal or hormonal-like function and/or cytokine-like function" is vague and indefinite. While "hormone" is well-defined in the art, the terms "hormonal-like function and/or cytokine-like function" are not and it is unclear precisely what activity is encompassed by the terms.

C) In Claim 1, the phrase, "is used in the diagnosis and/or therapy of autoimmun [sic] diseases, in particular diseases of the rheumatic group as systemic lupus erythematosus, rheumatoid arthritis or systemic sclerosis", includes a spelling error and comprises a sentence fragment that is uninterpretable. Specifically, it is unclear whether or not this sentence fragment is intended to comprise a limitation to the claimed invention.

D) In Claim 2, the phrase, "Effective part of a peptide" is vague and indefinite as it is not disclosed precisely what the peptide is "effective" for.

E) In Claim 2, the phrase, "at least one consensus sequence depicted as boxes of five amino acids whereby the C terminal is always A x K K K (x=A or P)" is vague and indefinite as the meaning of this phrase cannot be determined. In particular, the metes and bounds of this "consensus sequence" cannot be determined.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of

predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

A review of the instant specification shows that the peptides of the claims are fragments of histon [sic] proteins. In particular, the elected peptide of SEQ ID NO:6 appears to be a fragment consisting of amino acids 195-220 of the human histone H1 protein. The peptides are asserted to comprise antigenic determinants involved in rheumatic autoimmun [sic] diseases including systemic lupus erythematosus (SLE) rheumatoid arthritis (RA), systemic sclerosis, and sclerodermia [sic]. The peptides are disclosed as being used for the diagnosis and treatment of said diseases.

Regarding the treatment of rheumatic autoimmune diseases, the specification offers just a single paragraph at page 12 wherein it is disclosed that diseases such as SLE, RA, and scleroderma can be treated by the administration of the claimed peptides. No data is disclosed, and indeed, no theory or mechanism by which the peptides might provide an effective treatment is even proposed. Accordingly, it would take undue trials and errors to employ the claimed invention for the treatment of any disease.

Regarding the diagnosis of disease, the specification discloses only that a combination of H1 (187-211) (presumably this represents amino acids 187-211 of the human H1 histone protein) and H2B (1-35) (presumably this represents amino acids 1-35 of the human H2B histone protein) peptides bound antibodies from the sera of certain patients. Note it is not even clear how many patients of what type were tested because at page 7 the specification discloses that 122 SLE patients were tested whereas at page 8, the specification discloses that just 80 SLE patients and 42 "rheumatic" patients were tested. Regardless, the peptides of the assay were not the peptide of the claimed invention. Accordingly, the results disclosed in the specification disclose nothing regarding the use of the claimed peptide for the diagnosis of disease.

Thus, in view of the quantity of experimentation necessary, the lack of sufficient guidance in the specification, the lack of sufficient working examples, i.e., the specification discloses no data relevant to the use of the claimed peptide, the unpredictability of the art, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

1/3/07

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